K003534

DEC - 1 2000

510(k) Summary
PENTRA 5D Hematology Control

Date of Summary:	November 16, 2000
Company Name:	R&D Systems, Inc. 614 McKinley Place N.E. Minneapolis, MN 55413
Contact name:	Kenneth T. Edds, Ph.D. 612-379-2956, FAX 612-379-6580
Classification name:	multiparameter hematology control
Classification code:	81JPK Hematology Control mixtures for Quality Control
Product name:	PENTRA 5D Hematology Control
CFR section:	864.8625
Device Class:	Class II

Device to which substantial equivalence is claimed:
CBC COBAS 5 Hematology Control, manufactured by R&D Systems, Inc. 510(k) number: K940089

The product is an *in vitro* diagnostic reagent composed of human erythrocytes, mammalian leukocytes and mammalian platelets in a plasma-like fluid with preservatives. PENTRA 5D is composed of stable materials that provide a means of monitoring the performance of ABX hematology systems. PENTRA 5D is available in three levels and allows the control of multiple parameters including a 5 part differential. PENTRA 5D is used and tested in the same manner as patient samples.

Intended use: PENTRA-5D is a tri-level control designed for use in monitoring the accuracy and precision of the ABX hematology blood cell counters. Refer to the assay table for specific instrument models.

PENTRA 5D Hematology Control has an intended use that is identical to the predicate device. The technologies of the two devices are identical.

Nonclinical testing of 3 validation lots centered on the performance attributes of stability and precision. PENTRA 5D Hematology Control passed the acceptance criteria of remaining within the assay range over the life of the product. PENTRA 5D Control also demonstrated precision as indicated by the small standard deviations and %CVs obtained during testing. Expiration dating has been established at 60 days in the customers hands (closed vial) and 14 days, or 14 entries, open vial when stored at 2-8°C and handled according to instructions for use.

R & D Systems, Inc.
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC - 1 2000

Kenneth T. Edds, Ph.D.
Director, RA/QA
R & D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, Minnesota 55413

Re: K003534
Trade Name: PENTRA 5D Hematology Control
Regulatory Class: II
Product Code: JPK
Dated: November 16, 2000
Received: November 16, 2000

Dear Dr. Edds:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K003534

Device Name: PENTRA 5D Hematology Control

Indications for Use:
PENTRA-5D is a tri-level control designed for use in monitoring the accuracy and precision of the ABX hematology blood cell counters. Refer to the assay table for specific instrument models.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maheux

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003534

Prescription Use √ OR Over-The-CounterUse_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)